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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/551,740 04/18/00 MURRAY

A 5697.200-US

HM12/0925

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EXAMINER

ROBINSON, B

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

09/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/551,740

Applicant(s)

Murray Et. Al.

Examiner

Binta Robinson

Group Art Unit
1625



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-47 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-37 and 39-47 is/are rejected.

☒ Claim(s) 38 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 1-37 and 39-47 are generic to a plurality of disclosed patentably distinct species comprising the ring systems defined A^1 , A^2 , Ar and the radicals defined by k, n, Z, Q, m, R^5 , R^6 , M, Y and R^8 . Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Carol Razek on 9/14/2000, a provisional election was made with traverse to prosecute the invention of example 50 on page 55 of the specification. Affirmation of this election must be made by applicant in replying to this Office action.

3. Based upon the election of species, the examiner has examined the generic formula of formula I in claim 1 as follows:

A^1 =phenyl

A^2 =phenyl

k=1

n=0 to 3

Q=O, S, and N

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Ar=arylene, heteroarylene, or a divalent heterocyclic group which is optionally substituted with one or more halogen, C₁₋₆-alkyl, amino, hydroxy, C₁₋₆-alkoxy or aryl.

Y=oxygen, sulphur, or N

R⁸= the radicals are independently those defined in claim 1.

4. Claims 1-37 and 39-47 are Markush claims which are generic to the elected invention. The Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

5. Claims 1-37 and 39-47 are rejected on the grounds that the claims are drawn to an improper Markush group. In re Harnish, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not itself reason to render all the embodiments functionally equivalent.

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The improper Markush groups are ring systems A¹, A², k, n, Q, Ar, Y, R⁵, R⁶, and R8.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43 and 45 are rejected under 35 U. S. C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. Specifically, claims 43 and 45 are directed to a method of preventing a condition mediated by nuclear receptors, such as diabetes or obesity. There are no known cures for diabetes for instance, as well as no known preventative measures for diabetes.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 43 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of preventing or treating the various diseases mediated by nuclear receptors such as diabetes and/or obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are broader than the scope of enablement. For example, the specific dosage regimens for the administration of these compounds are not noted for the various conditions

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mediated by nuclear receptors. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1-5, 14, 17-34, 36, and 39-42 are rejected under 35 U. S. C. 102(a) as being anticipated by Wild. et. al. (See Reference N).

Wild et. al. teaches the instant compounds, compound 42, where R5 is -CONHCH₂Ph, and compound 1-Piperazinepropanoic acid, 4-[4,4-bis(4-fluorophenyl)butyl]-.alpha.-(2,4-difluorophenoxy)-ethyl ester. At page 30, line 50, see example 42, and at pages 1-38, see compound 1-Piperazinepropanoic acid, 4-[4,4-bis(4-fluorophenyl)butyl]-.alpha.-(2,4-difluorophenoxy)-ethyl ester.

11. Claim 38 as it pertains to the searched subject matter, is objected to because it depends on a rejected claim.

12. The elected species of example 50 on page 55 of the specification appears to be allowable.

13. The IDS filed 8/19/00 has been considered.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta Robinson whose telephone number is (703)306-5437.

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The examiner can normally be reached on Monday through Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703)308-0204. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

BMR

BMR

September 15, 2000

John Kight
JOHN KIGHT
SUPERVISOR EXAMINER
600 60